

The Mid-Atlantic Cancer Genetics Network

Consent to Participate



A regional center of the Cancer Genetics Network

**You are being invited to join
a research program called the
Mid-Atlantic Cancer Genetics Network.**

**This program is part of the
national Cancer Genetics Network,
which is sponsored by the National Cancer Institute
and is enrolling
people throughout
the United States.**



The Mid-Atlantic Cancer Genetics Network



What is the Cancer Genetics Network?

You are being invited to join a national program called the Cancer Genetics Network (CGN). The CGN, sponsored by the National Cancer Institute (NCI), is enrolling people throughout the United States. The Mid-Atlantic Cancer Genetics Network (MACGN), centered at Johns Hopkins University, is one of several sites involved in this program.



What is its purpose?

The main purpose of the CGN is to help scientists and health care providers find out more about the causes of cancer. This will help people and their doctors prevent, detect, or treat cancer in the future. The MACGN is inviting people who have had cancer or have a family history of cancer to be on a list of people, called a "registry," who may be willing to be part of future cancer research studies.

Some examples of future studies might include:

Identifying factors which affect a person's risk for getting cancer,

or

Studying different types of drugs or other treatments that might be used to prevent cancer.

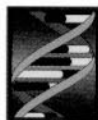
These types of studies need to have many people participate in order to get information that will be useful. Most research centers are not able to find enough people in their own areas to do these studies. The

CGN will help by keeping a nationwide list of people who are willing to be contacted about future studies. By combining volunteer participants from many centers, research may be done more quickly.



The CGN will also collect basic medical and family information on each participant. This information

will be updated every year and may be useful in answering some basic research questions about cancer and genetics.



What is required of people who join the Registry?

By enrolling in the CGN Registry, you would agree:

1. **To complete a 20-25 minute questionnaire** about your family history of cancer, personal medical history, lifestyle and reproductive information, and your diet.
2. **To be contacted once every year to update your information**, even if you do not take part in any future studies. To make this possible, you agree to inform MACGN of any changes in your contact information.
3. **To be contacted about future studies** for which you are eligible. Your name and contact information will be kept at Johns Hopkins. The information will not be released to any other researcher or center without your permission (see "Privacy/Confidentiality" section on page 5). If you qualify for any national CGN studies in the future, you will be contacted by the local MACGN site at Johns Hopkins. The study will be explained to you and you will be asked if you want to take part. You will not be involved in any future studies unless you give your permission. If you decide to take part in a future study, you will sign a separate informed consent at that time. Depending on the type of study, you may be asked to give your permission for release of additional medical records (including genetic test results if applicable). You may also be asked for more information, a blood sample, or tissue from a surgery you had in the past. You may be asked to give your permission for genetic testing on your blood or tissue sample for which you may or may not receive the results. In all cases, this information will not be linked with your name, only with an identification number. You may also be offered genetic counseling and testing which may provide you or your family with information about cancer risk or other genetic diseases.



It is possible that you may not be contacted about future research studies if you do not qualify for any of the proposed studies.



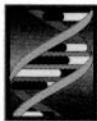
Will it cost me anything to be in the CGN?

You will not be paid for enrolling in the CGN. There will be no cost to you from being a part of the national registry. However, if you decide to take part in a future research study, there may be costs involved (for example, for genetic counseling or testing). You will be told about any possible costs before you agree to take part in any future study.



What benefits will I receive by being in the network?

There are no direct medical benefits to you from taking part in the CGN. However, you will receive information about causes, detection, prevention or treatment of cancer through a newsletter. If you do not wish to receive the newsletter, please tell the MACGN project coordinator (1-877-880-6188). You will have access to educational materials about cancer. You can find out about physicians or genetic counselors for cancer genetics services. You or your family may benefit from having access to future research studies and information about causes, detection, prevention or treatment of cancer.



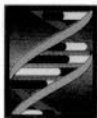
What are the risks of participating?

The possible risks of participating in the CGN registry include:

You may feel worried or sad when you are asked about your personal or family history of cancer. You may find it upsetting if you are contacted in the future to update your information or to be told about a research study for which you are qualified.

There is a small risk of loss of privacy from being a part of a national registry. Although every effort will be made to protect your privacy (see "Confidentiality" section on next page), it is possible that someone could find out against your wishes that you are in the national registry.

You may be at risk for discrimination by employers or insurance carriers. Sometimes genetic information or knowledge that a person has been a part of a genetic research study may cause an employer or insurance carrier to discriminate against that person by denying a job or health insurance. **Registering in the CGN will probably not result in discrimination.**



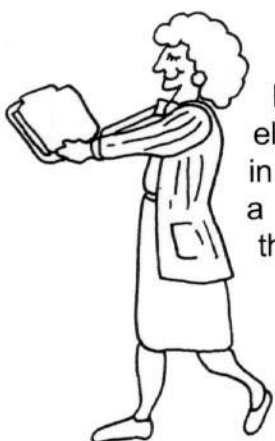
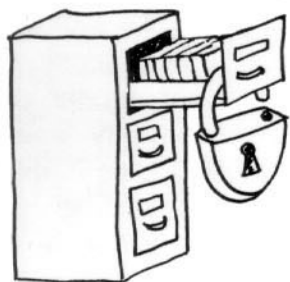
Voluntary Participation

You do not have to take part in the CGN. Your participation in the CGN is *voluntary*. Whether or not you choose to participate will not affect your current or future medical care at Johns Hopkins Hospital. You are also free to stop taking part in the CGN at any time. If you choose to withdraw from the CGN, all of the information that can identify you will be destroyed.



How is my confidentiality protected?

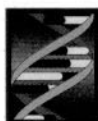
Every effort will be made to protect your privacy. All of your personal information, including your name, birth date, address, etc. will be kept by the MACGN. Your tissue samples, if they are obtained by the MACGN, will also be in a secure place at the Johns Hopkins Medical Institutions. Before the information from your questionnaire is sent to the national registry, all information that can identify you will be removed. Your information will be kept in the national registry using only a number, and not your name.



Because your name and contact information will only be kept at Johns Hopkins, you will only be contacted by the MACGN staff, unless you give your permission for someone else to contact you. (For example, you may consent to take part in a CGN study that involves a telephone survey. When you sign a consent for that study, you would be asked for permission for that researcher to contact you directly.)

This research program is covered by a Certificate of Confidentiality issued by the National Cancer Institute on behalf of the Secretary of the Department of Health and Human Services. The Certificate protects against the involuntary release of information about you collected during the course of this project, although such information can be released if you or your guardian requests it in writing. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this project in any legal proceedings at the Federal, State, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the Certificate does not prevent the review of your research records under some circumstances (for example, under the Federal Food, Drug and Cosmetic Act or during the course of an internal program audit or evaluation).





For questions or comments, please call us at

410-614-6334 (in Baltimore)

or

1-877-880-6188 (toll-free)